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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,888	07/17/2003	Robert Gurny	4-20437D	7666

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CORPORATE INTELLECTUAL PROPERTY
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EAST HANOVER, NJ 07936-1080

EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/623,888

Applicant(s)

GURNY ET AL.

Examiner

Gollamudi S Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8 and 12-31 is/are pending in the application.
- 4a) Of the above claim(s) 27-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8 and 12-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The amendment dated 7-2-2004 is acknowledged.

1. Newly submitted claims 27-31 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the originally presented claims are composition claims drawn to nanoparticles which are coated with polymers which are resistant to gastric juices and soluble in intestinal juices and process claims which make this product. The newly submitted claims are process claims wherein a hydrophilic polymer such as polyvinyl alcohol is used and the product produced by the specific process. Polyvinyl alcohol is a water-soluble polymer, which is attacked by both acids and bases. This means the composition is soluble in gastric juices and therefore, a new invention. (Condensed chemical dictionary (page 943) is cited of interest in this context.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 27-31 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims included in the prosecution are 1-6, 8, and 12-26.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 8, 12-15, 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawata et al (4,343,789).

Kawata et al disclose fine powders of active agents of low solubility coated with various copolymers of met acrylic acid and met acrylic esters or hydroxypropylmethyl cellulose phthalates. The fine particles are mixed with additives and filled in capsules for oral delivery. The particles can be lyophilized. (Abstract, col. 2, lines 13-44, col. 5, lines 10-20, Examples and claims). Since the fine powders are pulverized for 16 hours in a vibrating ball mill, the burden is upon applicant to show that this process does not result in nanoparticles.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1-6, 8 and 12-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawata et al (4,343,789) or Stainmesse (5,133,908) of record by themselves or in combination.

Kawata et al disclose fine powders of active agents of low solubility coated with various copolymers of met acrylic acid and met acrylic esters or hydroxypropylmethyl cellulose phthalates. The fine particles are mixed with additives and filled in capsules for oral delivery. The particles can be lyophilized (abstract, col. 2, lines 13-44, col. 5, lines 10-20, Examples and claims).

Stainmesse as discussed in the previous action while disclosing nanoparticles of lipophilic active agents teaches that these nanoparticles can be coated with polymers such as aceto phthalate of polyvinyl, acetophthalate of cellulose (enteric polymers) among others. One of the methods of preparation involves mixing the polymer in an aqueous medium to the active agent in acetone. The particles can be lyophilized (note abstract, col. 2 line 63 through col. 3, line 3, Examples 9 and 15 in particular and claims). It would have been obvious to one of ordinary skill in the art to prepare the nanoparticles of water insoluble drugs and coat them enterically with the expectation of obtaining at least similar results based on the suggestion and guidance provided by Stainmesse.

What is lacking in Kawata et al is the specific teaching that the powders are of nanoparticles sizes. However, assuming that they are not of nano sizes, it would have been obvious to one of ordinary skill in the art to prepare particles of any sizes with the expectation of obtaining intestinal delivery since the site of delivery depends upon the enteric coating and does not depend upon the size of the particles. One of ordinary skill in the art would prepare particles of desired sizes depending upon the purpose for which they are used. One of ordinary skill in the motivated to further to prepare

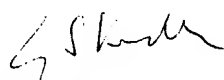
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nanoparticles since the reference of Stainmesse teaches that these particles are used for routine delivery of water insoluble drugs. Alternately it would have been obvious to one of ordinary skill in the art to coat the nanoparticles of Stainmesse with enteric polymers since such a coating would enable the active agents not to dissolve in the stomach but in the intestines as also taught by Kawata.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615